REMARKS/ARGUMENTS

Examiners response to previous arguments

The Examiner states that the use of the words "stratum corneum" on page 7, line 10 of the specification is not an obvious error. In support of this contention the Examiner states "Additionally, Figure 3 of the instant specification discloses, "Move laser across skin to explode the graphite particles and reveal the underlying skin". Therefore, this disclosure clearly indicates that skin is removed."

Applicant respectfully disagrees. The specification is amended to remove the sentence on page 7, line 10, which reads as follows: "As the particles explode, they cause the removal of the stratum corneum and the mineral oil 20 penetrates into the epidermis producing hydration of the epidermis by retarding the evaporation of water (see Fig. 2)." This sentence is removed because it is in error and is inconsistent with the entire specification. The language in step 43 of Fig. 3 says nothing about removing skin. There is no reasonable basis for inferring such a meaning from the language in step 43 of Fig. 3. Applicant declares that the ordinary and reasonable meaning of this language is that when the particles are made to explode by the laser light, they disappear and one can see the skin that was underneath the particles before they were made to explode (see Applicant's declaration). This would be the obvious meaning to one of ordinary skill in the art. In order to eliminate any possible confusion, step 43 in Fig. 3 has been amended to remove the phrase "and reveal the underlying skin" without prejudice or disclaimer.

Claim rejections under 35 USC §112

The new matter added to the specification has been removed.

The Examiner states, in the section titled "The State of the Art: http://www.surgervencyclopedia.com/La-PaiLaser-Skin Resurfacing.html, that this website discloses, "Laser skin resurfacing involves the application of laser light to the skin in order to remove fine wrinkles and tighten the skin surface. The purpose of laser skin resurfacing is to use the heat generated by extremely focused light to remove the upper to middle layers of the skin." Thus, the instant specification discloses using "skin resurfacing" on page 6 to render the cosmetic benefit and the state of the art indicates that

"skin resurfacing" is the removal of skin. Therefore, if the skin is not removed, as argued by applicant since only 1-2 pulses are used, then the skin is not resurfaced and the cosmetic benefit is not attained.

The applicant respectfully disagrees with the Examiner. The prior art cited by the examiner does not teach that "skin resurfacing" is the removal of skin. That prior art reference teaches that skin resurfacing can be accomplished by removal of skin. It does not teach that that is the only way to achieve skin resurfacing. Thus it is not logical to conclude that if skin is not removed then the skin is not resurfaced. In fact, Applicant has discovered a novel and inventive process to achieve skin resurfacing without removing skin, to the extent that the epidermis remains intact. The laser light used by applicant has no effect on the skin by itself. Explosion of the particles with the laser light by itself produces no effective treatment of the skin. Applicant has discovered that combining the retinoic acid treatment (which by itself does not produce an effective treatment) with the exploding particle treatment does, in fact, produce an effective treatment of the skin. Thus, Applicant has found a way to produce skin rejuvenation while leaving the epidermis intact. There is no such method taught or suggested in the prior art.

The Examiner concludes that "Therefore, the prior art indicates that some skin either in the stratum corneum or beneath the stratum corneum will be removed by laser surgery to attain cosmetic benefits."

The Applicant agrees with the Examiner that the prior art indicates that some skin either in the stratum corneum or beneath the stratum corneum will be removed by laser surgery to attain cosmetic benefits. However, Applicant's method does not include laser surgery. Applicant's method involves exploding particles on the skin with a laser light in which the laser light itself has no effect on the skin. Furthermore, the exploding particles in applicant's method leave the epidermis intact and do not, by themselves, improve the appearance of the skin. It is the combination of retinoic acid with the exploding particles that produces the cosmetic benefit.

Claim Rejections under 35 USC §103

Claims 21,23-29,33-37 were rejected by the Examiner under 35 U.S.C. §103(a) as being unpatentable over Goldberg et al (Skin resurfacing utilizing a low-fluence Nd:Y

AG laser, J Cutan Laser Ther. 1999:1:23-27) in view of Alster (Combined Laser Resurfacing and Tretinoin Treatment of Facial Rhytides, Cosmetic Dermatology, Volume 10, No. 11, November 1997) in view of Ho et al (Dermatologic Surgery. 1995 December, 21(12),1035-7) and Kye YC (Dermatologic Surgery 1997 October, 23(10): 880-883).

The Examiner states that Goldberg et al teach nonablative skin resurfacing using 1064-nm Q-switched Nd:Y AG laser potentiated by a carbon solution at a fluence of 2.5J/cm, repetition rate of 1-10 HZ, and a pulse duration of 6-20ns to treat rhytides (wrinkles). The treatment sites were treated at 4 and 8 weeks. Improvement in wrinkles, skin texture, and elasticity was seen. Goldberg does not teach the application of retinoic acid.

The Examiner states that Alster teaches cutaneous laser resurfacing recently has advanced the treatment of facial rhytides (wrinkles) to provide a youthful look. Combining laser resurfacing with long-term skin care using tretinoin emollient cream provides maximal, long-lasting improvement of facial rhytides.

The Examiner states that Ho et al teach laser resurfacing in pigmented skin and skin with acne scars with a CO2 laser. The method includes: (a) The patients were treated with 0.05% tretinoin, hydroquinone, and desonide cream nightly for 2-4 weeks prior to the laser treatment (b) The Ultrapulse 5000C CO2 laser with a setting of 250-450 mJ per pulse, or the Silk Touch flashscanner at the setting of 5-7 W, O.2-second pulse duration, and 4-mm (M) spot size, is used on the skin; (c) tretinoin, hydroquinone, and desonide and broad spectrum sunscreen is also used postoperatively. Ho discloses the reduction of hyperpigmentation with regular use of tretinoin, hydroquinone, and desonide cream both pre- and postoperatively along with use of broad-spectrum sunscreen after treatments.

The Examiner states that Kye teaches a method of resurfacing pitted facial scars including acne scars, chicken pox scars, and small pox scars, with a pulsed Er:Y AG laser. The method includes: step (a) prior to laser surgery, the patients are treated with 0.05% tretinoin (note 0.05% reads on about 0.1 %) nightly for two to four weeks; step (b) the patient is then treated with Er:YAG laser at a setting of 500mJ/pulse and 3.5-4.5 Watts with a pulse frequency of 7-9 Hz. Kye discloses that after 4-6 laser passes, pinpoint bleeding occurred; step (c) two weeks after laser treatment % tretinoin and 1 % hydrocortisone cream is applied for 2-4 weeks.

The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references and utilize a pre-treatment and post-treatment regimen prior to the laser therapy taught by Goldberg. One would have been motivated to do so since Alster teaches combining laser resurfacing with long-term skin care using tretinoin emollient cream provides maximal, long-lasting improvement of facial rhytides. Therefore, it is prima facie obvious for a skilled artisan to utilize tretinoin to work in conjunction with laser treatment to provide long lasting results.

In Alster's method there is substantial trauma to the skin. Within the first 24 hours after treatment the skin turns bright red, swells, and oozes a clear yellowish liquid. Ice packs and ointments or bandages are prescribed for use. The possible side effects include skin lightening or darkening, infection, acne, scarring, and prolonged redness. After the laser surgery the skin is sensitive and each case must be evaluated continuously.

In Ho's method there is persistent erythema and hyperpigmentation can occur.

In Kye's method there is pinpoint bleeding requiring wet gauze treatment. Erythema occurs and is aggravated by the use of retinoic acid.

In Goldberg's method there is removal of skin cells resulting in erythema. In some cases there is pinpoint bleeding. Golberg states that his procedure is nonablative. Ablation is defined as removal of material from the surface of an object. Thus, Goldberg's method is ablative, although apparently less ablative than those of Alster, Ho, and Kye. Goldberg uses the method of Tankovich as described for hair removal which explodes carbon particles a sufficient number of times to remove skin and produce erythema.

All of these above methods remove skin and do not leave the epidermis intact. The prior art teaches that, with laser surgery, some skin must be removed to obtain a beneficial effect on the appearance of the skin. Tankovich teaches that carbon particles must be exploded a sufficient number of times to remove skin, and that removing skin is necessary to obtain a beneficial effect on the appearance of the skin. Tankovich also teaches that, until that sufficient number of times is achieved, carbon particles can be exploded without removing skin cells. This is shown very clearly in Figures 6 and 7 in US Patent No. 5,423,803, with a corresponding explanation in column 3, lines 30 to 40.

A similar description is shown in Figures 3E and 3F in US Patent No. 6,036,684, with a corresponding explanation in column 4, lines 35 to 45. Thus, the prior art teaches that carbon particles can be exploded on the skin in such a way as to leave the epidermis intact, but being ineffective in treating the skin.

The Applicants submit that in order to make a valid rejection based on a *prima facie* case of obviousness, a combination of references must satisfy the requirements of *KSR International* v. *Teleflex Inc.*, 127 S.Ct. 1727,82 USPQ 2d. 1385 (2007). Under the *KSR* rule, three basic criteria are considered. First, some suggestion or motivation to modify a reference or to combine the teachings of multiple references has to be shown. Second, the combination has to suggest a reasonable expectation of success. Third, the prior art reference or combination has to teach or suggest all of the recited claim limitations. Factors such as the general state of the art and common sense may be considered when determining the feasibility of modifying and/or combining references. The Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness based on this standard.

The Examiner's argument is as follows. Goldberg teaches skin resurfacing using exploding carbon particles but does not teach the use of retinoic acid in combination with the use of exploding particles. To cure this deficiency, the Examiner proposes to combine Goldberg with Alster, Ho, and Kye, wherein Alster, Ho, and Kye teach the use of laser surgery resurfacing in combination with retinoic acid. According to the Examiner, replacing the laser method of resurfacing with the exploding particle method of resurfacing in Alster, Ho, and Kye would, therefore, be obvious.

The Applicant respectfully disagrees with such a rationale. Some suggestion or motivation to combine the teachings Goldberg with those of Alster, Ho, and Kye must be shown. The Examiner does not take into account that Applicant's method leaves the epidermis normal and intact (See specification, page 10, line 12). There is no reason to combine Goldberg with Alster, Ho, and Kye because Goldberg does not leave the epidermis intact. Applicant's method of exploding particles, by itself, is ineffective in treating the skin (see Applicant's declaration). Goldberg's method, by itself, is effective in treating the skin. Applicant's method and Goldberg's method are, thus, not the same. Combining Goldberg with Alster, Ho, and Kye does not provide a method for combining

retinoic acid with a method which leaves the epidermis intact and which, by itself, is ineffective in treating the skin. One of ordinary skill in the art would know that exploding particles on the skin while leaving the epidermis intact would be ineffective in treating the skin (see Applicant's declaration). One of ordinary skill in the art would not be motivated to combine a method ineffective in treating the skin with retinoic acid, especially with a dosing of retinoic acid which is ineffective by itself, which is the case in Applicant's method (see Applicant's declaration).

The combination of references does not suggest a reasonable expectation of success of effective treatment of the skin by combining a method of exploding particles on the skin which leaves the epidermis intact and which, by itself, is ineffective, with application of retinoic acid. There also is no reasonable expectation of success when the dosing of retinoic acid by itself is ineffective.

The combination of references do not teach or suggest the limitation in amended claim 21 of a method of exploding particles which, by itself, is ineffective in treating the skin. The combination of references do not teach or suggest the limitation in claim 25 wherein exploding a contaminant on the surface of the skin of the face with laser light is completed within about 4 minutes. It is inherent in such a limitation that the exploding of particles by the present method would be ineffective in treating the skin by itself, and one of ordinary skill in the art would know this (see Applicant's declaration). The combination of references do not teach or suggest the limitation of amended claim 33 that retinoic acid is applied topically without producing side effects.

It is well established law that secondary considerations may be used to show that a claim rejected under35 U.S.C. § 103(a) was not obvious. The courts may look to secondary considerations in determining the obviousness of an invention that include long-felt but unresolved need, failed attempts by others, initial skepticism, subsequent praise, commercial success, and copying by others. *Graham* v. *John Deere Co.,* 383 U.S. 1 (1966). Secondary indicia of non-obviousness, such as the evidence concerning, among others, unexpected results, must be considered whenever obviousness is an issue. The Applicant respectfully directs the Examiner's attention to the evidence of such secondary consideration as unexpected results which clearly demonstrate that claim 21 is patentably non-obvious over the combination of cited references, and requests the Examiner to

consider this evidence. Such evidence can be found directly in the instant application. The specification on page 9, lines 7-10 state:

> In the next steps **42** and **43** a laser beam is scanned over the area treated with the activating solution so as to clean substantially all of the mixture from the skin surface by exploding or fracturing the carbon or graphite particles in the oil. This scanning process takes from about 2 to 10 minutes to complete on the face, usually about 4 minutes.

> On page 3, lines 9-10 the specification further states: An advantage of the present invention is the production of a chronic wound in the high dermis with no damage to the epidermis.

> On page 10, line 12, the specification further states: Furthermore, this has been accomplished leaving the epidermis intact and normal.

Applicant states in her declaration that a person of ordinary skill in the art would know that exploding the carbon particles to complete the process on the face within about four minutes, leaving the epidermis intact, undamaged, and normal, would require exploding the carbon particles insufficiently to produce any cosmetic or beneficial effect by itself. One of ordinary skill in the art would not reasonably expect the result of skin rejuvenation and improved appearance of the skin by further adding intermittent topical application of retinoic acid to this process of exploding particles on the skin of the face. The prior art would not reasonably predict such a result because there is nothing in the prior art that teaches or suggests that combining retinoic acid with an exploding particle method which by itself is ineffective in treating the skin would produce skin rejuvenation. It is submitted that the results from adding retinoic acid to the skin in combination with exploding particles on the skin, which by itself is ineffective in treating the skin, to produce sustained rejuvenation of the skin unquestionably qualify as unexpected. Such results would also not be reasonably predicted.

The Examiner has indicated that the specification is not enabling to one of

ordinary skill in the art. Applicant respectfully disagrees and provides a declaration stating the reasons why one of ordinary skill in the art would have no difficulty in practicing the invention as claimed based upon the disclosures in the specification. The parameters for producing the necessary laser light are described in sufficient detail in the specification and in the Tankovich prior art (US Patent Nos. 5,423,803 and 6,036,684). Although the Tanovich prior art describes several methods for applying the laser light to carbon particles, there is only one method disclosed in the Tankovich prior art that describes exploding carbon particles in such a way that skin cells are not removed by the process and the epidermis remains intact, as discussed above. This method is described in no uncertain terms in Figures 6 and 7 in US Patent No. 5,423,803, with a corresponding explanation in column 3, lines 30 to 40, and in Figures 3E and 3F in US Patent No. 6,036,684, with a corresponding explanation in column 4, lines 35 to 45. One of ordinary skill in the art would have no problem identifying this method and applying it. The specification states that "Although the photomechanical laser process of *Tankovich* is considerably safer than the standard photothermal laser treatments and leaves the epidermis intact, this photomechanical laser process is relatively ineffective in treating the skin and has not been commercially successful." The only method in the Tankovich prior art that is ineffective in treating the skin is the one referenced above (Figures 6 and 7 in US Patent No. 5,423,803, with a corresponding explanation in column 3, lines 30 to 40, and in Figures 3E and 3F in US Patent No. 6,036,684, with a corresponding explanation in column 4, lines 35 to 45). Based upon the disclosures in the specification cited above:

> In the next steps **42** and **43** a laser beam is scanned over the area treated with the activating solution so as to clean substantially all of the mixture from the skin surface by exploding or fracturing the carbon or graphite particles in the oil. This scanning process takes from about 2 to 10 minutes to complete on the face, usually about 4 minutes.
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> On page 3, lines 9-10 the specification further states: An advantage of the present invention is the production of a chronic wound in the high dermis with no damage to the epidermis.
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> On page 10, line 12, the specification further states: Furthermore, this has been accomplished leaving the epidermis intact and normal.

One of ordinary skill in the art would have no problem understanding that the laser light of the present invention is applied only sufficiently to explode the particles without damaging the epidermis because it is inherent in the method. Knowing that the object is to explode the carbon particles without damaging the epidermis, it is then easy for one of ordinary skill in the art to know how much time to expose the particles to the laser. That amount of time is that which explodes the particles but does not affect the epidermis. Further guidance is provided in the specification by the description that "This scanning process takes from about 2 to 10 minutes to complete on the face, usually about 4 minutes" (page 9, lines 7-10), and "A single treatment of the skin of the face can be completed within four minutes" (page 4, lines 3-4). One of ordinary skill in the art would also know that this method, by itself, of exploding the carbon particles would not produce an effect on the epidermis because it is inherent in the method. This is in addition to knowing that Tankovich teaches only one procedure of exploding carbon particles that does not remove skin from the epidermis.

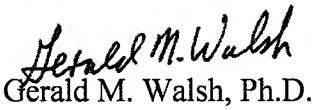
Claim 21 has been amended to recite that the exploding of the contaminant on the surface of the skin by itself is ineffective in treating the skin. Support for this amendment if found on page 2, lines 19-21, and is inherent in the procedure in that the procedure leaves the epidermis intact and is completed on the face within about 4 minutes (page 3, line 7, 9-10; page 4, lines 3-4; page 7, line 14; page 9, lines 7-10; page 10, line 12; page 17, lines 3-5). Claim 33 has been amended to include the further limitation that retinoic acid is applied without producing side effects. This amendment has support in the specification on page 3, line 18.

In view of the above remarks and arguments, amended claim 21 is not obvious over Goldberg in view Alster, Ho, and Kye and is, therefore, allowable. Claims 23-29 and 33-34 are allowable as depending from an allowable claim.

CONCLUSION

For the foregoing reasons, Applicant respectfully requests that the Examiner reconsider the application in light of the amendments and arguments and that all claims in the application be permitted to proceed to allowance.

Respectfully Submitted,



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